



Atty. Docket No. 1501-1131

*#8 Response*  
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*PATENTS*

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Knut IRGUM et al.

Confirmation No. 1048

Serial No. 09/831,162

GROUP 1723

Filed May 7, 2001

Examiner E. Therkorn

CHROMATOGRAPHY METHOD AND A  
COLUMN MATERIAL USEFUL IN SAID  
METHOD

**RECEIVED**

RESPONSE

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**TC 1700**

Commissioner for Patents

Washington, D.C. 20231

Sir:

Responsive to the determination of lack of unity set forth in the Official Action of September 24, 2002, Applicants hereby provisionally elect Group I, claims 15-23, drawn to a sorbent, with traverse.

As for the election of species requirement imposed in the Official Action, Applicants hereby elect  $\omega$ -dialkylaminoalkylsulfonic acid groups. Applicants respectfully submit that claims 19, 21 and 23 read on the elected species. In accordance with the outstanding Official Action, it is believed that claim 15 is generic.

The grounds for traverse are as follows:

As the Examiner is aware, a determination of lack of unity is proper only when the claims of a group lack a "special technical feature" relative to another group. It is the burden

of the Patent Office to establish the lack of a special technical feature.

As to the determination of lack of unity imposed in the outstanding Official Action, it is respectfully submitted that the Patent Office fails to carry its burden in showing that the claimed invention lacks unity. In this regard, the Examiner's attention is respectfully directed to PCT Rule 13.2. PCT Rule 13.2 provides that a determination of a special technical feature must be art-based. While the outstanding Official Action cites WENZHI as showing the special technical feature of the present invention, Applicants respectfully traverse this assertion.

The present invention is directed to a sorbent suitable for use as a stationary phase in elution chromatography, the core of said sorbent comprises an organic resin and said sorbent has a plurality of covalently bonded non-aromatic zwitterionic groups on its surface. Applicants believe that WENZHI fails to disclose or suggest the claimed invention.

WENZHI together with several articles by the same author (HU et al., Anal. Chem 65:2204-2208 (1993); HU et al., Anal Chem 66:2514-2520 (1994) are discussed on p. 5, lines 5-26, in the present specification.

The studies of HU et al. have been carried out with commercial octadecyl silica columns, which have been dynamically and non-covalently coated with zwitterionic surfactant reagents. WENZHI states that "In order to test the electrostatic effect of

the zwitterionic stationary phase formed on the surface, two types of zwitterionic stationary phases were used. One was an ODS solid phase onto which CHAPS micellar particles were coated and formed (referred to as "CHAPS stationary phase"). While the other was an ODS solid phase onto which NaTDC micellar particles were coated and formed (referred to as "NaTDC stationary phase").

However, WENZHI does not disclose covalently binding zwitterionic groups to a carrier. While the word "immobilized" is used in an ambiguous manner in the abstract and corresponding "Summary of the Invention", Applicants believe that the word "immobilized" is used as a synonym for "coated". Applicants note that the "Detailed Description of the Invention" does not discuss or even refer to "immobilization". Thus, it is believed that the concept of immobilized is only found in WENZHI due to an erroneous translation from Japanese.

A column according to WENZHI is used to simultaneously separate inorganic cations and anions, such as  $I^-$ ,  $SCN^-$ ,  $NO_2^-$ ,  $NO_3^-$ ,  $IO_3^-$ ,  $Na^+$ ,  $K^+$ ,  $Rb^+$  and  $Cs^+$ , using an aqueous solution of 1 mM copper sulphate as mobile phase (see WENZHI, col. 11, line 40 - col. 12, line 5). WENZHI states that the enzyme alpha-amylase has been purified from saliva on detergent-modified hydrophobic silica.

However, it is important to note that this enzyme passed through the column without retardation. WENZHI interprets

this result as being due to a size exclusion effect (See: col. 12, lines 29-31). Moreover, no other protein was assayed simultaneously. Finally, Applicants point out that the stationary phase can leak out from the column because the phase is not covalently bound to the carrier. It is unacceptable in the pharmaceutical industry to use a separation column where part of the material may leak out together with compounds that are to be used in pharmaceutical preparations.

In the claimed invention, the column material of claim 15 is a sorbent having a plurality of covalently bonded non-aromatic zwitterionic groups on its surface. The column material of WENZHI comprises a carrier coated with zwitterionic detergents. Thus, it is believed that claim 15 is novel and non-obvious in light of WENZHI. As claims 16-23 are dependent on claim 15, it is believed that claims 16-23 are unique and non-obvious for the same reasons.

It is believed that WENZHI fails to disclose or suggest the "special technical feature" of the claimed invention. It is believed that WENZHI fails to disclose or suggest an improved sorbent suitable for use as a stationary phase induction chromatography of proteins and other biomolecules by covalently binding a plurality of non-aromatic zwitterionic groups to the surface of an organic resin.

Thus, Applicants believe that the Official Action fails to comply with the requirements of PCT Rules 13.1 and 13.2. As

noted above, a proper lack of unity determination would require the proper citation of a reference showing the special technical feature of the present invention. As WENZHI fails to disclose the special technical feature of the claimed invention, it is believed that the Official Action does not provide a proper citation showing the special technical feature of the claimed invention. Absent such a citation, the lack of unity determination is improper as a matter of law.

In light of the above discussion, therefore, it is believed that the Applicants are entitled to an action on the merits for all of the pending claims in their full scope, in the present application. Such action is accordingly respectfully requested.

Respectfully submitted,

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